

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ammann et al.

Confirmation No.: 8957

Application No.: 10/564,452

Group Art Unit: 1794

Filing Date: January 12, 2006

Examiner: E. Gwartney

For: HIGH FIBRE HIGH CALORIE
LIQUID OR POWDERED NUTRITIONAL
COMPOSITION

Attorney Docket No.: 7444/US/PCT

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I hereby state as follows:

1. My experience and qualifications are as follows:

Ph.D. in Human Nutrition & Biochemistry
25 years of research experience
in Clinical Nutrition (University level)
(industry)

2. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein. I am also familiar with the study discussed below at Exhibit B that tested the tolerance of a composition having an increased amount of fiber similar to the presently claimed composition compared to a similar, non-fiber composition, which was known to be well tolerated. Further, I am familiar with the study discussed below at Exhibit E and related to the synergistic effect observed between fructooligosaccharides and acacia gum on the bifidogenic effect.

3. I have reviewed the outstanding Office Action dated December 1, 2009 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the references cited therein as well as the pending claims.

4. The present invention is directed, in part, to compositions including protein, a source of digestible carbohydrates, and a source of dietary fiber, and methods of using same. Specifically, the present disclosure relates, in part, to compositions having an energy density of 1.3-1.8 kcal/ml and more than 2.5g/100 ml dietary fiber. The source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight pea outer fiber, and 20-40% by weight fructooligosaccharides.

5. Malnutrition or gastro-intestinal disorders, more generally gut-discomfort or pain, may simply be the consequence of unhealthy or unbalanced nutritional behavior. However, malnutrition may also affect perfectly healthy people, be it due to increased energy expenditure, as is the case with athletes or other sportsmen following intensive physical exercise, be it in other circumstances such as pregnancy. The occurrence of malnutrition in various situations during life, in particular with elderly or ill people, has thus led mainly to high calorie and high nutrient compositions. Consumption of such compositions, however, was often problematic, especially in patients with unbalanced gut flora and with gut impairment, because of gut pain or discomfort.

6. With respect to the present disclosure, it has been surprisingly found that a nutritional composition including 4.5 to 6g protein/100ml composition and acacia gum as a soluble fiber in addition to pea outer fiber and fructooligosaccharides demonstrated good shelf-stability for 8 months and was judged to have a good taste. The composition was rich in fiber and improved intestinal transit, gut flora and gut comfort. Accordingly, the claimed invention provides a nutritional composition that has a high energy content and improves digestive tract health. The presently claimed compositions also provide the advantage of a surprisingly low viscosity that results from use of the claimed fiber blend. Despite the high proportion of soluble non-starch polysaccharides and oligosaccharides, and the high amount of total fiber of the

compositions, the compositions have a surprisingly low viscosity and are surprisingly well tolerated.

7. Attached hereto as Exhibit B, is a summary of a controlled study demonstrating the tolerability of a composition having increased amounts of fiber similar to the presently claimed composition, as compared to a similar, non-fiber composition with known tolerability. The study performed was a double blind placebo controlled and randomized study having eighty-nine elderly volunteers that were asked to answer questionnaires on gut comfort and well-being. The elderly were allocated to two treatment groups in equal numbers. One group received Clinutren® 1.5 as an oral supplement and the other group received Clinutren® 1.5 Fiber as an oral supplement (the compositions of which are attached hereto as Exhibits C and D, respectively). The oral supplements were given in 200 ml cups twice a day targeting a daily intake equal to 400 ml and 600 Kcal during a five week period.

8. Before, during and after the study period summarized at Exhibit B, various anthropometric, biochemical, and fecal microbiological measurements were taken. All adverse events that occurred during the study were reported and recorded regardless of severity or relation to the nutritional intervention. The volunteers also filled out an eight-question questionnaire on gut comfort and well-being four times over a six week period.

9. As is described in detail in the summary of Exhibit B, there were no reported negative effects of either of the oral supplements. In particular, the increased fiber supplement (Clinutren® 1.5 Fiber), which includes a similar fiber content, including pea outer fiber, to the presently claimed compositions, did not promote any undesired abdominal symptoms. Accordingly, the increased fiber supplement (Clinutren® 1.5 Fiber) was surprisingly as well tolerated as a similar, non-fiber composition (Clinutren® 1.5).

10. Further, attached hereto as Exhibit E, is a summary that describes a randomized, double-blind study used to determine if a blend of fructooligosaccharides and acacia gum stimulates intestinal growth of bifidobacteria more effectively than each of the carbohydrates

alone. The study performed utilized ninety-six healthy volunteers that were divided into three groups. A first group consumed 200 ml/day of skimmed milk with fructooligosaccharides (6g/day). A second group consumed 200 ml/day of skimmed milk with acacia gum (6g/day). The third group consumed 200 ml/day of skimmed milk with fructooligosaccharides and acacia gum ((3g fructooligosaccharides + 3g acacia gum)/day).

11. As described in Exhibit E, a synergy was observed between fructooligosaccharides and acacia gum on the bifidogenic effect. Accordingly, using blends of fructooligosaccharides and acacia gum, an effective dose of prebiotic can be optimized in order to reduce potential abdominal discomfort related to the intake of fructooligosaccharides.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date:

January 27, 2010

Print Name

Claudia Roessle